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Food and Drug Administration
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★ First Match

NOTICES

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[Docket No. 94N-0006]

Proposed Switch of Acyclovir from Prescription to Over-the-counter Status; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding the proposed over-the-counter (OTC) availability of orally administered acyclovir. The purpose of the hearing is to solicit information from, and the views of, interested persons, including scientists, professional groups, and consumers, on the issues and concerns relating to the proposed OTC availability of acyclovir for the acute and suppressive management of recurrent genital herpes.

DATES: The public hearing will be held on Thursday, May 19, 1994, from 8 a.m. to 3 p.m. Submit written notices of participation and comments by April 29, 1994. Written comments will be accepted until June 20, 1994.

ADDRESSES: The public hearing will be held at the Parklawn Rldg., conference rms. D and E, 5600 Fishers Lane, Rockville, MD 20857. Submit written notices of participation and comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number 94N-13006. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

I. Background

SUPPLEMENTARY INFORMATION: Acyclovir is a synthetic purine nucleoside analogue with in vitro inhibitory activity against herpes simplex viruses 1 and 2 and varicella zoster virus. An oral formulation of acyclovir was approved in 1985 with initial indications for the treatment of first episode and recurrent genital herpes. Since 1985, FDA has also approved the oral formulation of acyclovir for the treatment of herpes zoster and chickenpox, and for the suppression of recurrent genital herpes.

Burroughs-Wellcome has discussed publicly its intention to seek approval for a supplemental new drug application (NDA) to switch acyclovir from prescription to OTC status (e.g., at the July 1993 International Herpesvirus Workshop). Burroughs-Wellcome has also discussed publicly that this application is currently under review at FDA (e.g., at the October 1993 Interscience Conference on Antimicrobial Agents and Chemotherapy).

The proposed switch would apply only to 200-milligram capsules with proposed indications for the acute and suppressive management of recurrent genital herpes. If the supplemental NDA is approved, acyclovir would be the first systemically administered antimicrobial agent available without prescription in the United States, and it would also be the first OTC product for the treatment of a sexually transmitted disease.

II. Scope of the Hearing

In light of the many complex scientific and public health issues raised by this application, FDA is soliciting broad public participation and comment on the potential merits and disadvantages of this proposed switch. The agency encourages investigators with information relevant to this switch, as well as other interested persons, to respond to this notice. Examples of issues that are of interest to the agency include the following: (1) The implications of unrestricted availability of acyclovir for the transmission and asymptomatic shedding of herpes simplex virus; (2) the incidence and clinical significance'of acyclovir-resistant herpes simplex virus; (3) the ability of patients to self-diagnose genital herpes (i.e., without consultation with a physician); (4) the potential for misuse for unapproved OTC indications (such as for chickenpox, shingles, and other viral illnesses); (5) the potential for adverse effects on the fetus; and (6) general issues of safety (and the incidence of adverse drug events) during widespread, unrestricted use. In addition, FDA is actively seeking the views of professional and consumer groups regarding the implications of this application for their constituent populations.

Elsewhere in this issue of the Federal Register, FDA is announcing a joint meeting of the Antiviral and the Nonprescription Drugs Advisory Committees under 21 CFR part 14. This meeting will allow FDA to receive comments from the advisory committee members as well as the general public. Those persons or groups presenting views at the public hearing before the Commissioner need not make a second presentation at the advisory committee meeting, because views presented in the earlier hearing will be taken into consideration in the joint advisory committee meeting.

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the

public hearing will be held in accordance with 21 CFR part 15. The presiding officer will be the Commissioner of Food and Drugs or his designee. The presiding officer will be accompanied by a panel of Public Health Service employees with the relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written notice of participation with the Dockets Management Branch (address above) prior to April 29, 1994. To ensure timely handling, any outer envelope should be clearly marked with the docket number 94N-0006 and the statement "Acyclovir Hearing." Groups should submit two copies. The notice of participation should contain the person's name, address, telephone number, affiliation if any, brief summary of the presentation, and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. FDA will allocate the time available for the hearing among the persons who file notices of participation as described above. If time permits, FDA may allow interested persons attending the hearing who did not submit a written notice of participation, in advance, to make an oral presentation at the conclusion of the hearing.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, it will be placed on file in the Dockets Management Branch under the docket number 94N-0006.

Under § 15.30 the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of their presentation.

Public hearings, including hearings under part 15, are subject to FDA's guideline (21 CFR part 10, Subpart C) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings. Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

Any handicapped persons requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until June 20, 1994. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (address above) by June 20, 1994.

Dated: March 1, 1994.

Michael R. Taylor,
Deputy Commissioner for Policy.

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